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Educating Hispanics About Clinical Trials and Biobanking

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Abstract
Hispanics are under-represented in clinical research. To ensure that the Hispanic population benefits from advances in public health and medicine, including personalized medicine, there is a need to increase their participation in clinical trials and biobanking. There is a great need for improving awareness and addressing concerns individuals may have about participation. The purpose of this study was to adapt, implement, and evaluate educational materials about clinical trials and biobanking for Hispanic individuals. We adapted existing materials based on focus group data. We then trained four promotoras de salud to deliver education to Hispanic adults in community settings in Houston, TX. The promotoras educated 101 Hispanic adults, 51 on biobanking and 50 on clinical trials. Study staff administered brief pre- and post-test questionnaires that measured benefits, barriers, norms, self-efficacy, and intention to participate in either clinical trials or biobanking. Our sample was predominately female (83%) and Spanish-speaking (69%) and made less than $25,000 a year (87%). This intervention increased perceived benefits of participating in biobanking and clinical trials, self-efficacy for donating biospecimens, and intention to participate in biobanking if invited. Perceived barriers to participating declined. This study demonstrated that brief education can result in improved perceptions and attitudes related to participation in biobanking and clinical trials, and could increase participation. Researchers and practitioners could use these educational materials to educate Hispanic community members on clinical research potentially increasing participation rates in the future.

Keywords Biobanking · Clinical trials · Cancer education · Hispanics

Introduction

With the emergence of personalized medicine, an approach for disease prevention and treatment that takes into account individual variability in genes, environment, and lifestyle, it is essential for diverse groups to participate in clinical trials and to donate biological samples [1, 2]. However, minority populations have historically low participation rates in clinical research and are under-represented in biobanks [3–6]. This is particularly true for Hispanics who represent only 2% for participation in biobanking and 5% in clinical trials [3, 7, 8]. Additionally, while cancer is the leading cause of death among Hispanics [9], only 1.3% of eligible Hispanic cancer patients participate in cancer-related clinical trials [10].

Researchers have identified a host of barriers and facilitators to low Hispanic participation in biobanking and clinical trials. Some of the barriers include language, distrust of the medical system, concerns about privacy, lack of knowledge or awareness, fear of side effects, and fear of being experimented on [11–14]. Factors that positively influence participation include altruism, desire to contribute to advancing science, having a family member with disease, the opportunity to access health care, and monetary incentives [11, 12, 15, 16]. Improving a participant's knowledge of and attitudes toward clinical research can influence self-efficacy and intention to participate [17–19]. However, this education should be delivered in a culturally appropriate manner, and researchers have identified a need for more culturally appropriate approaches

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for Hispanics to reduce barriers and facilitate participation in clinical trials [12, 20]. Thus, there is an urgent need to develop and test interventions designed to improve knowledge and attitudes related to participation in clinical trials and biobanking.

To address the low participation among minorities, a few existing educational interventions have specifically targeted certain racial/ethnic groups, including Asians and Pacific Islanders [21–23] and African-Americans [24–26]. However, only a few interventions have targeted Hispanics [27, 28], whose participation barriers and facilitators may be different from those of other racial/ethnic groups [14]. Furthermore, many existing clinical trial or biobanking interventions target cancer patients in clinical settings but not the general population. Some biobank [29] and cancer prevention [30–32] studies require healthy participants. Educating the general population about clinical trials and biobanking can help with recruitment of healthy Hispanic participants in these types of studies. It would also improve communication between providers and newly diagnosed Hispanic patients because patients would already know about clinical research and more easily understand the options.

Because of the clear need for culturally appropriate educational materials for Hispanics, we adapted existing educational materials on biobanking and clinical trials for Hispanics and trained *promotoras de salud* to deliver the adapted intervention to 101 Hispanic adults in community settings in Houston, TX. We evaluated the impact of the curriculum on perceived barriers, benefits, norms, self-efficacy, and intention to participate in clinical trials and biobanking.

Methods

Understanding Knowledge and Attitudes

To inform eventual educational materials, we conducted 15 focus groups with Hispanics in Texas designed to better understand knowledge and perceptions of clinical trials and biobanking [11, 12]. We found that there was a lack of knowledge about biobanking and clinical trials, a distrust of health research, and a fear of harm from participating in biobanking or a clinical trial. However, with enough information and assurance that the researchers have good intentions, participants said they would be willing to participate for altruistic reasons. Based on these findings, we determined that more education for the Hispanic community was needed.

Identification and Adaptation of Existing Materials

To identify materials, we conducted a literature review of existing interventions for either biobanking or clinical trials or both, including those specific to Hispanics. We also reached out to the Community Networks Program Center (CNPC), a program funded by the National Cancer Institute. As one of these CNPCs [U54CA153505], our team at the University of Texas Health Science Center at Houston School of Public Health was aware of the emphasis on reducing the unequal burden of cancer experienced by racial/ethnic minority populations by applying CBPR approaches to community education and intervention testing, among other aims [33]. We identified two sets of existing Spanish language materials on biobanking and clinical trials. These included one PowerPoint presentation on both clinical trials and biobanking and two accompanying brochures from the University of Texas Health Science Center at San Antonio [U54CA153511] [34, 35] and a video on biobanking from Moffitt Cancer Center [U54CA153509] [36].

In reviewing these existing materials, we noted that while many of the barriers and facilitators to clinical trial and biobanking participation identified in the 15 focus groups were addressed, others were not. To assess the appropriateness of the existing materials and the need for adaptation to the Hispanic population in Houston, we conducted six focus groups during which we shared the material with participants. Results indicated that participants preferred in-person education that provided the opportunity. They also noted that they wanted a video that clearly and succinctly explained the topic, and that written materials were only appropriate if accompanying an oral, in-person session. They also made suggestions about shortening the printed material and made additional recommendations about changes to the wording and formatting. Thus, based on both sets of focus groups, we made decisions on what adaptions we would make to the existing materials.

We adapted the materials using IM Adapt, a systematic approach to adapt health promotion interventions for a new population or setting [37]. We created two distinct educational curriculums, addressing the topics of biobanking and clinical trials separately, as we envisioned that those educating on one topic may not necessarily be educating on the other. Therefore, we first divided the content of the original Trevino-Whitaker et al. [34] PowerPoint presentation accordingly, separating the content into two presentations. To the presentations, we made the following adaptations: revised the definitions of biobanking and clinical trials, added two interactive activities and added true/false questions that encouraged participation and discussion, emphasized the need to discuss biobanking or clinical trials with a doctor, and added a list of questions to ask before deciding whether to donate a biospecimen or participate in a clinical trial. For the clinical trial presentation only, we added information explaining the randomization process and include current clinical trials recruiting in the Houston area.

The original Trevino-Whitaker et al. [34] materials also included two brochures, one about clinical trials and one about

donating biospecimens. We kept these two brochures separate, to accompany their respective presentation. Given the recommendations on length of the written materials from our focus groups, we edited the clinical trial brochure from 12 pages to four pages. The length of the biobanking brochure stayed the same, as a single-page brochure, with content on the front and back. Based on feedback from our focus groups, we included additional written information on the informed consent process and a patient's rights and used text formatting to emphasize key points in the brochure.

Lastly, we made no adaptations to the biobanking video developed by Moffitt Cancer Center. This video was shown following the biobanking presentation only. The video provided testimonials about donating biospecimens, and focus group participants found the video useful and appropriate.

The final adapted educational curriculum included a set of materials for educating on clinical trials (a PowerPoint presentation and a take-home brochure) and another set for educating on biobanking (a PowerPoint presentation, take-home brochure, and a video). All educational sessions include a group discussion during which study participants could ask questions and explore topics in greater detail if desired.

Training *Promotoras de Salud*

Study staff trained four *promotoras de salud* (community health workers) to deliver both sets of educational curricula (clinical trials and biobanking) in both Spanish and English. The in-person training for each curriculum lasted about 2 hours each. *Promotoras* then completed practice sessions to ensure they were knowledgeable of the content and comfortable with the group format delivery.

Participants

Participants were recruited in-person or through flyers distributed at community centers, community clinic waiting rooms, and health fairs. Study staff and *promotoras* invited interested participants to attend an educational session held at a community center. We recruited and educated a convenience sample of 101 adult participants, 51 assigned to the biobanking group and 50 to the clinical trial group.

Data Collection and Measures

The University of Texas Health Science Center's Institutional Review Board approved the study. Study staff first obtained written informed consent and then administered a pre-test questionnaire to each participant. The *promotoras* then delivered the educational sessions. After each session, study staff administered a post-test questionnaire, and participants received $10 gift cards.

Pre- and post-test questionnaires included questions assessing psychosocial factors that could be related to participation in clinical trials/biobanking. These included perceived barriers, perceived benefits, descriptive and subjective norms, self-efficacy, and intention to participate in clinical trials and/or biobanking (see Table 1). These items were developed by the study team. For the constructs with two items (barriers, benefits, and subjective norms), we averaged the two to create a composite score.

We also collected basic demographic information at pre-test, including participant's race, ethnicity, gender, education, employment status, income, health care coverage, and whether he/she had a primary health provider. The post-test included additional questions to determine the best delivery channels and venues for clinical trial and biobanking education, and questions related to how well the participant understood the information, and whether they would share the information with others. Some of these items were adapted from questionnaires accompanying the original materials [34].

Statistical Analyses

We used descriptive statistics to assess the distribution of the psychosocial variables of interest. Because the variables were not normally distributed, we used the Wilcoxon signed rank test to test the null hypothesis of no difference between pre- and post-test scores. We conducted separate analyses for clinical trial and biobanking data. We used Proc Multtest, SAS version 9.4, to adjust for multiple comparisons of the outcomes and the Holm method, which controls the family-wise error rate without assuming independence.

Results

Participant Characteristics

Table 2 shows the demographic characteristics of each group. Both groups were mostly female, spoke mostly Spanish, had an income of less than $25,000 a year, and had a high school education or less. The biobanking group was on average 42 years old; the clinical trial group was 39 years old on average. Only a few participants had heard about biobanking or clinical trials; even fewer had ever participated.

Effect of the Educational Curriculum

Biobanking Between the pre- and post-tests, there were statistically significant increases in perceived benefits, descriptive norms, and self-efficacy for donating biospecimens (Table 3). We also observed statistically significant increases in intention to participate if invited. There were also statistically significant decreases in perceived barriers of biobanking

Table 1 Pre- and post-test psychosocial measures

Construct	No. of items	Item	Response options
Barriers	2	I have concerns about how [donating biospecimens to a biobank/participation in clinical trials] will affect my personal health and safety. I am worried that if I [donate biospecimens to a biobank/participate in clinical trials] my health information may not be kept confidential.	Strongly disagree (1) to strongly agree (5)
Benefits	2	[Donating biospecimens to a biobank is/Clinical trials are] important for improving health research. If I [donate biospecimens to a biobank/participate in clinical trials], it will be useful to others in the future.	Strongly disagree (1) to strongly agree (5)
Descriptive norms	1	I think that others like me [donate biospecimens to a biobank/participate in clinical trials].	Strongly disagree (1) to strongly agree (5)
Subjective norms	2	My doctor would want me to [donate biospecimens to a biobank/participate in clinical trials]. My friends and family would want me to [donate biospecimens to a biobank/participate in clinical trials].	Strongly disagree (1) to strongly agree (5)
Self-efficacy	1	How sure are you that you could [donate biospecimens to a biobank/participate in a clinical trial]?	Very unsure (1) to very sure (5)
Intentions	1	If invited, how likely is it that you would [donate biospecimens to a biobank/participate in a clinical trial]?	Not at all likely (1) to extremely likely (5)

participation. Unexpectedly, there was a decrease in perceived subjective norms (the belief that others want them to participate).

Clinical Trials Between the pre- and post-tests, there were statistically significant increases in perceived benefits of clinical trials and descriptive and subjective norms for clinical trial participation (Table 3). There were also statistically significant decreases in perceived barriers to clinical trial participation. While there were increases in self-efficacy and intention to participate in clinical trials, these changes were not significant.

Delivery of Educational Materials

All 101 participants indicated that the discussion helped them better understand biobanking or clinical trials and that they would share the information with their family and friends. All but one individual (clinical trial group) thought the information presented was easy to understand. Participants in the biobanking group indicated preferred formats for receiving the education included oral presentation (76.5%), oral with video (76.5%), printed materials (58.8%), and the Internet (51%). Those same participants were asked where they think people would like to receive the information delivered during the educational sessions. Most said community events (82.4%), doctor's office (52.9%), schools (29.4%), and home visits (15.7%).

Participants in the clinical trial group indicated preferred formats were oral presentation (78%), oral with video (64%), printed materials (52%), and the Internet (56%) (data not shown). Like the biobanking group, the clinical trial group said they preferred to attend sessions at community events (72%), doctor's office (64%), schools (46%), and home visits (32%).

Discussion

We successfully implemented an educational curriculum targeting clinical trial and biobanking participation for Hispanics in Houston, TX. This was the first time many participants reported they had heard the terms *biobanking* or *clinical trial*, which indicated the need for education in this community. In the biobanking group, only 17.6% had heard about biobanking and 9.8% reported that they had participated in biobanking, though this was prior to delivering the education. In the clinical trial group, 46% of the participants had heard about clinical trials, which was a much higher proportion than those who heard of biobanking. However, only 6% of those participants reported ever participating in clinical trials.

We saw that the adapted education intervention increased perceived benefits and reduced perceived barriers to participation in both the biobanking and clinical trial groups. This was consistent with previous studies that reported increased positive attitudes related to clinical trials in clinical and community populations. For example, Jacobsen and colleagues' (2012) brief, multimedia, psycho-educational intervention effectively improved attitudes toward clinical trials among primarily non-Hispanic White patients with cancer and increased willingness to participate in clinical trials. Similarly, Du and colleagues (2009) used an educational video that improved attitudes toward clinical trials and increased trial enrollment among non-Hispanic White and African-American patients with newly diagnosed breast cancer.

Table 2 Demographic characteristics of educational session participants

Demographic characteristic	Received biobanking education $N = 51$ (%)	Received clinical trial education $N = 50$ (%)
Mean age in years, (age range)	42.3 (18–75)	39.4 (18–75)
Gender		
Female	42 (82.4)	42 (84.0)
Male	9 (17.6)	8 (16.0)
Language		
Spanish	35 (68.6)	35 (70.0)
English	16 (31.4)	15 (30.0)
Employed		
Yes	25 (49.0)	13 (26.0)
No	26 (51.0)	37 (74.0)
Years of school		
0–6	17 (33.3)	14 (28.0)
7–12	28 (54.9)	29 (58.0)
12+	6 (11.8)	7 (14.0)
Household income		
< $10,000	22 (43.1)	19 (38.0)
$10,001–$25,000	22 (43.1)	25 (50.0)
$25,000+	6 (11.8)	6 (12.0)
Do not know	1 (2.0)	0
Health insurance		
Yes	24 (47.1)	23 (46.0)
No	25 (49.0)	27 (54.0)
Do not know	2 (3.9)	0
Primary health provider		
Yes	24 (47.1)	25 (50.0)
No	27 (52.9)	25 (50.0)
Heard about biobanking/clinical trials	9 (17.6)	23(46.0)
Participated in biobanking/clinical trials	5 (9.8)	3 (6.0)

Self-efficacy and intention to participate in biobanking significantly increased in our study, the former finding being consistent with at least one previous study [27]. However, we did not find statistically significant differences in self-efficacy and intention to participate in clinical trials, the former which has been seen in another clinical trial educational intervention [28]. Given the contrast between these findings, it appears that this brief educational intervention was more effective for biobanking education than for clinical trial education at least for changing self-efficacy and intention. This may be because the thought of participating in a clinical trial may seem more complicated and time-consuming than participating in biobanking. Thus, an intervention to increase participation may require more time for providing examples of trials and what participation might entail to increase both the belief in their ability to participate and their intention to do so. Another reason may be that the participants did not think they would be provided the opportunity to participate in a clinical trial given their current use of health care and the fact that almost no one had ever been offered participation. Manne and coworkers (2014) found that self-efficacy is a mediator between barriers and clinical trial preparedness, where fewer perceived barriers are associated with higher levels of self-efficacy and, in turn, greater levels of preparedness. Although we saw significantly decreased perceived barriers related to clinical trial participation, this may not have been sufficient to change self-efficacy or intention to participate. A longer intervention, perhaps even with multiple sessions, that allows additional time to answer questions and more fully address barriers and self-efficacy may be more effective for clinical trial education.

We also found significant changes for subjective norms, indicating that others who are important to the participant may have influence on his/her decision to participate in biobanking or clinical trials. Our results for subjective norms were inconsistent, showing significant change for both types of research but in the unexpected direction for biobanking. The results may indicate that the influence of others was important for biobanking and clinical trial participation, pointing to the potential value of including other stakeholders in the process of addressing the multi-level barriers to participation [38]. Therefore, the close family and community ties seen among Hispanics may point to the importance of holding educational sessions in the community and including participants' friends and family [39, 40].

Table 3 Differences in psychosocial variables between pre-test and post-test

Variable	Pre-test mean	Post-test mean	*p* value
Biobanking			
Barriers	2.92	2.35	0.034
Benefits	4.46	4.76	0.015
Descriptive norms	3.78	4.33	0.034
Subjective norms	4.10	3.75	0.005
Self-efficacy	3.59	4.39	0.001
Intention to participate	3.22	3.69	0.005
Clinical trials			
Barriers	2.74	2.02	0.012
Benefits	4.58	4.94	0.012
Descriptive norms	3.98	4.64	0.005
Subjective norms	3.20	4.74	0.001
Self-efficacy	3.68	4.14	0.084
Intention to participate	3.40	3.70	0.084

Wilcoxon signed rank test using the Holm method to control the family-wise error rate

Given that more than half of participants indicated that they would like to receive information on clinical trials and biobanking at the doctor's office, health care providers should be trained to provide recommendations or referrals to clinical research. We must use caution however, in recommending this approach only, as about half of our sample did not have health insurance and did not have a primary health care provider. Additionally, participants also indicated that they would like to receive this information in community spaces.

This study demonstrated the feasibility of using *promotoras* trained in biobanking and clinical trial content to deliver an educational intervention about these topics to Hispanic participants in a community setting. The *promotoras* were familiar with the Hispanic community in Houston and had successfully delivered cancer education to improve screening, prevention, and access to health care service. *Promotoras* are effective because they are part of the community they serve, speak the language of the people, and know the cultural traditions [41]. These qualities help build trusting relationships and enhance the exchange of health and resource information. Future interventions should consider the *promotora* model when delivering education about biobanking and clinical trials to minority communities in order to ensure a more culturally appropriate intervention [27].

Given participants' preference for receiving the information in video format, future interventions could incorporate mobile technology to enhance learning as well as tailoring. This could also accelerate the dissemination of biobanking and clinical trial educational materials. Additionally, more research is needed to better understand both intention and actual participation. For example, McIntyre and colleagues (2017) evaluated the use of such health communication modalities as mailed materials, mailed materials plus follow-up calls, and *charla* (face-to-face group discussion) to change knowledge, attitudes, self-efficacy, and intention to participate in biobanking. Their pilot trial found the *charla* approach increased knowledge the most but had the lowest participation rate. Researching differences in effectiveness among various communication channels is needed to optimize intervention delivery and increase participate rates.

Although we did not specifically measure knowledge changes before and after the educational intervention, all participants reported that the discussion helped them better understand biobanking and clinical trials. The lack of a control condition in this study limited our ability to attribute changes to the intervention; however, since the post-test immediately followed the intervention, it is unlikely that the participants were exposed to other sources of information on these topics. The findings should be confirmed with larger randomized, controlled trials and particularly those that can measure behavioral (participation) outcomes in addition to intention. Because we recruited our sample in community areas where people were seeking other social services and assistance, the sample may have included participants who were more likely to participate in clinical research or who were inclined to seek out information. Participants also indicated that they preferred oral presentations and receiving information about biobanking and clinical trials at community events. Given that these questions were asked after receiving education in an oral format at a community health center, often the location of many community health events, there is a chance that individuals answered in a socially desirable way. Finally, the educational sessions were presented during the day, which may have excluded working individuals. These two limitations (location and time of educational sessions) may explain the reason that the majority of the participants (82.4%) were female and unemployed (51%). Future studies should expand the sample to include more male and employed participants. Additionally, we did not collect data to document the participant's country of origin. There is a possibility that there are differences in biobanking and clinical trial participation among Hispanics from different countries of origin or that the sample population was primarily from one particular country [42]. However, based on the demographics of the neighborhood center that we recruited and delivered the intervention, the majority of the members are of Mexican and Central American origin. Thus, future interventions might require adapting the Spanish educational materials for appropriateness to Hispanics from different countries of origin [42]. Despite these limitations, our study represents an important step in developing and evaluating educational intervention to increase clinical trial and biobanking participation among Hispanics.

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Compliance with Ethical Standards

The University of Texas Health Science Center's Institutional Review Board approved the study.

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